REMARKS

The remainder of this Reply appears appropriate subheadings for the convenience of the Examiner.

Claim Amendments

Claims 5, 12 and 14 were amended to more clearly define Applicants' claimed invention. Support for amendments to the claims can be found throughout the specification and previously amended Claims 5, 12 and 14. No new matter has been added. Entry is requested.

Rejection of Claims 5-7 and 12-14 Under 35 U.S.C. § 112, First Paragraph

Claims 5-7 and 12-14 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner stated that the reasons for the rejection were as set forth on page 2 of the Office Action dated October 7, 2003. On page 2 of the Office Action dated October 7, 2003, the Examiner stated that Claims 5-7 and 12-14 failed to comply with the written description requirement because the claims contained subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner further stated in the October 7, 2003 Office Action that the claimed invention was directed to the treatment of different cartilage or bone pathology using a retinoid receptor agonist and that the specification discloses examples of structures of some compounds within the scope of what is claimed. In addition, the Examiner further stated that there is no evidence that there is any structure/function relationship between the disclosed retinoid receptor agonist compounds and any others that may be found using the claimed invention and that structurally identifying characteristics of a group of retinoid receptor agonist was not disclosed. In the present Office Action, the Examiner also stated that the specification provides no guidance to enable one of ordinary skill in the art to use the invention commensurate in scope and encompassing treatment of bone related disorders using any compound which is a retinoid receptor agonist.

As stated at Section 2163, page 2100-173 of the May 2004 revised edition of the Manual of Patent Examining Procedure ("MPEP"), there are several factors to consider when determining

the adequacy of the written description of a specification to support the claimed subject matter, which include the following:

> Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

(Emphasis added).

Further, as stated at Section 2163.02, page 2100-177 of the MPEP:

> Whenever the issue [adequacy of written description] arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. [Citations omitted]. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. [Citations omitted].

(Emphasis added).

As noted in Section 2163 II(A)(3)(ii) (pages 2100-174 to 2100-175) of the MPEP, the written description requirement for claims directed to the use of known compounds can be satisfied by reference to a known genus of compounds. In particular, as stated on page 2100-174 of the MPEP, in citing the U.S. Court of Customs and Patent Appeals in *In re Herschler*, 591 F.2d 693 (CCPA 1979):

> disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "[claims directed to the] *use* of *known* chemical compounds in a manner auxiliary to the invention must

> have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds."

(Emphasis in original *In re Herschler*, 591 F.2d at 702).

In Applicants' claimed invention, compounds considered to be "retinoid receptor agonists" and their use in a "manner auxiliary to the invention" are well known. For example, at column 8, line 1 and column 151, line 44 of U.S. Patent No: 5,958,954 (hereinafter "the '954 Patent"); column 7, line 43 and column 125, line 57 of U.S. Patent No: 5,877,207 (hereinafter "the '207 Patent"); and column 7, line 48 and column 115, line 13 of U.S. Patent No: 6,008,204 (hereinafter "the '204 Patent") the term "retinoid receptor agonist" is employed. Copies of the '954, '207 and '204 Patents are attached to this Reply as Exhibits A, B and C, respectively.

In addition, retinoid receptor agonists are described generally in the specification. For example, at page 4, lines 25-28, retinoid receptors are described:

> At the molecular level retinoids exert their biological effects through two families of nuclear receptors, retinoic acid receptors (RARs) and retinoid X receptors (RXRs), which belong to the supra family of steroid/thyroid/vitamin D3 nuclear receptors.

An agonist is defined on page 6, lines 24-25 of the specification as:

> As used herein, "agonist" means a compound that will stimulate the ligand-mediated transactivational activity of the specified retinoid receptor.

Further, on page 21, lines 17-25, the use of retinoid receptor agonists are described:

> In another embodiment the instant invention is drawn to the use of retinoid receptor agonists as positive regulators of endochondral ossification. In this embodiment are provided methods for (a) enhancing the reparative process during fracture repair, (b) treating congenital conditions in individuals who may exhibit poor or retarded growth and ossification, (c) ameliorating osteoporosis, and (d) stimulating and modulating intramembrane ossification through treatment with retinoid receptor agonists.

> Congenital conditions of poor and retarded ossification may included [sic], by way of example only and not of limitation, spondyloepiphyseal dysplasia congenita, skeletal dysplasias, hip dysplasia, and multiple epiphyseal dysplasias.

Therefore, contrary to the Examiner's statement that the specification does not describe in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention, retinoid receptor agonists are described in the specification using "descriptive means, [such] as words" and "functional characteristics" (see, for example, page 4, lines 25-28, and page 6, lines 24-25) and their use in treating cartilage and bone pathologies (see, for example, page 21, lines 17-25) is described. The specification provides a written description that conveys with reasonable clarity to those skilled in the art that Applicants were in possession of the claimed invention. Thus, the specification meets the written description requirements of 35 U.S.C. § 112, first paragraph as applied to Applicants' claimed invention as set forth in Claims 5-7 and 12-14.

SUMMARY AND CONCLUSION

The specification provides an adequate written description to support Claims 5-7 and 12-14 by meeting the requirements of 35 U.S.C. § 112, first paragraph. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the Applicants' undersigned attorney.

Respectfully submitted,

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